

REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested. Claims 1-20 and 30-37 were pending. (Applicants note that claim 37 is not acknowledged in the "Office Action Summary" of Paper No. 19, although this claim is addressed in the Office Action rejection). As set forth above, Applicants hereby submit new claims 38-54. Support for the new claims may be found in the application as originally filed, in part, at page 8, lines 19-28, and Examples 3 to 11 (*see, e.g.*, claims 38-43); see also original claims 21 to 29 on page 35 through page 36 (*see, e.g.*, claims 44-54). Applicants respectfully request joinder of use claims 42 to 50 upon the allowance of a generic product claim, as provided by 37 CFR §1.141(b) and MPEP § 806.5(i). No new matter has been added. Therefore, claims 1-20 and 30-54 are currently pending.

REJECTIONS UNDER 35 U.S.C. § 103(a)

In the Office Action, claims 1-20 and 30-37 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,628,788 (Pinchuk) in view of U.S. Patent No. 6,605,294 (Sawhney) and U.S. Patent No. 6,113,629 (Ken). More specifically, it is alleged that it would have been obvious for a person having ordinary skill in the art to coat the stent graft of Pinchuk with a hydrogel that releases a drug that promotes *in vivo* adhesion as taught by Sawhney or Ken, to prevent the migration of the stent graft.

Applicants respectfully traverse this ground of rejection and submit that Pinchuk, Sawhney and Ken, taken alone or in combination, fail to teach or suggest the claimed invention and, further, would not have motivated a person having ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success. Briefly, where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under §103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also

have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991).

In the instant case, the cited references meet neither of these criteria. Pinchuk provide a graft material suitable for use with an endoluminal self-expanding stent (*see* Pinchuk, at column 3, lines 12-27). The problem addressed by Pinchuk is the identification of graft material that is deformable and decreases to one half to one tenth of its original diameter when the ends of the material are pulled apart (*see* Pinchuk, at column 3, lines 38-45). The problem addressed by Applicants' invention, namely unwanted movement of the graft after it has been inserted into a vessel, is not addressed by Pinchuk. Instead, Pinchuk teaches away from the instant invention by describing that stents are used in conjunction with graft material to bridge aneurysms because the stent helps, *inter alia*, to fix the graft in place (*see* Pinchuk, at column 2, line 67 through column 3, line 4). In other words, the stent is sufficient to anchor the graft in place. Moreover, Pinchuk is concededly silent with regard to the use of an agent that induces the *in vivo* adhesion of the stent graft to vessel walls, much less a stent graft that releases such an agent. Furthermore, Pinchuk is merely cumulative stent graft art to that already identified in the instant specification (*see, e.g.*, specification at page 7, line 5 through page 8, line 2; Pinchuk is identified on page 7, line 21). Therefore, Pinchuk fails to teach or suggest a stent graft comprised of an endoluminal stent and a graft, wherein the stent graft releases an agent that induces the *in vivo* adhesion of the stent graft to vessel walls.

Applicants respectfully submit that the disclosure of Sawhney fails to remedy the deficiencies of Pinchuk and, consequently, the combination of Pinchuk with Sawhney fails to teach or suggest the instant invention. Sawhney discloses substantially dehydrated hydrogel material that rehydrates and expands rapidly after being placed in a moist tissue environment, which results in wedging the swollen hydrogel in the tissue (*see* Sawhney, column 4, line 59, through column 5, line 4). Sawhney also discloses the use of self-anchoring swellable hydrogels to deliver therapeutic agents to a desired site, such as a tumor (*see* Sawhney, column 13, lines 43-51). Sawhney further provides that a dehydrated hydrogel can be used to coat the graft portion of a stent graft so that hydration of the coating on the stent graft enable the graft to become anchored and "tightly wedged" in place (*see* Sawhney, column 13, lines 16-41).

However, Sawhney does not teach or suggest that a dehydrated hydrogel can be used as a mechanism for inducing the *in vivo* adhesion of a stent graft to vessel walls. Instead, Sawhney teaches away from the use of any agent with a hydrogel for inducing *in vivo* adhesion of a stent graft to vessel walls according to the instant invention because the hydrogel swelling would be sufficient to wedge (*i.e.*, mechanically set) the stent graft in place. In addition, Sawhney emphasizes that the important feature of his invention is the ability of the hydrogel to hydrate and expand volumetrically, and compositions for enhancing such hydration, so that the hydrogel will occlude vessel openings or be anchored in tissue (*see* Sawhney, Examples 11, 15, and 16). Hence, a person having ordinary skill in the art would not be motivated to modify Sawhney to arrive at the instant invention. Furthermore, because Sawhney already discloses a stent graft, the addition of Pinchuk (who discloses only a stent graft) fails to teach or suggest the instant invention. That is, the combination of Sawhney and Pinchuk fails to teach or suggest every limitation of the claimed invention.

Applicants further submit that the disclosure of Ken fails to remedy the deficiencies of Pinchuk and Sawhney and, therefore, the combination of these references fails to teach or suggest the instant invention. Ken discloses a hydrogel as a carrier for a therapeutic agent, such as human growth factors, to treat aneurysms (*see* Ken, Abstract). Ken further teaches that once introduced into an aneurysm, the hydrogel crosslinks to occlude blood flow to the aneurysm and the therapeutic agent promote growth of a cellular layer across the neck of the aneurysm (*see* Ken at column 4, lines 34-40). However, Ken fails to teach or suggest the use of any kind of medical device, much less a stent graft comprised of an endoluminal stent and a graft wherein the stent graft releases an agent that induces the *in vivo* adhesion of the stent graft to vessel walls. In fact, Ken teaches away from the use of stent grafts by explicitly asserting that "sealing [an aneurysm] with adhesive, blocking it with a stent, or placement of a vasoocclusive device to occlude it may not be completely effective in healing the vascular damage" (*see* Ken at column 2, lines 60-65-40). Ken provides hydrogels that are sufficient to block blood flow to an aneurysm and to induce tissue growth without the use of a medical device. Hence, a person having ordinary skill in the art would not be motivated to modify Ken in view of Pinchuk and Sawhney to arrive at the instant invention.

Moreover, Applicants respectfully submit that the mere fact that the teachings of the prior art *can* be combined or modified, or that a person having ordinary skill in the art is *capable* of combining or modifying the teachings of the prior art, does not make the resultant combination *prima facie* obvious, as the prior art must also suggest the desirability of the combination (*see, e.g., In re Mills*, 16 U.S.P.Q.2d 1430, Fed. Cir. 1990; *In re Fritch*, 23 U.S.P.Q.2d 1780, Fed. Cir. 1992). Applicants also submit that when prior art references require a selective combination to render obvious a subsequent invention, there must be some reason for the combination *other* than the hindsight gleaned from the invention itself. To this end, reasons must be provided in the Office Action to show that a person having ordinary skill in the art, confronted with the same problems as the instant inventors and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *See In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998). In this case, the combination of Pinchuk, Sawhney and Ken fails to teach or suggest the desirability of forming a stent graft according to Applicants' claimed invention.

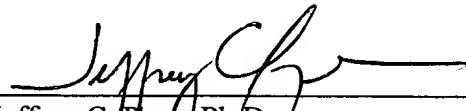
In sum, Applicants respectfully submit that a *prima facie* case of obviousness has not been set forth in the Office Action. In particular, no evidence has been provided that, at the time of filing the instant application, a person having ordinary skill in the art would have been motivated to arrive at the claimed invention given the disclosures of the cited references. Accordingly, Applicants respectfully submit that the instant claims satisfy the requirements of 35 U.S.C. § 103(a) and, therefore, request that this rejection be withdrawn.

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Reply to Office Action dated January 30, 2004

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims pending in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is urged to contact the undersigned attorney if there are any questions prior to allowance of this matter.

Respectfully submitted,
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